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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/824,027	04/14/2004	Jennifer E. Van Eyk	PTQ-0058	6007
7590 02/15/2006 Licata & Tyrrell P.C. 66 East Main Street Marlton, NJ 08053			EXAMINER DESAI, ANAND U	
			ART UNIT 1653	PAPER NUMBER

DATE MAILED: 02/15/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	Application No.	Applicant(s)	
	10/824,027	EYK ET AL	
	Examiner	Art Unit	
	Anand U. Desai, Ph.D.	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 18 November 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1 and 13-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1 and 13-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

### **DETAILED ACTION**

1. This office action is in response to Amendment filed on November 18, 2005. Claims 3-12 have been cancelled. Claims 1, and 13-20 are currently pending and are under examination.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### **Withdrawal of Rejections**

3. The rejection of claims 1, 13-16, 19, and 20 under the judicially created doctrine of obviousness-type double patenting is withdrawn based on the filing of a terminal disclaimer.

4. The rejection of claims 13-15, 19, and 20 under 35 U.S.C. 112, second paragraph, as being indefinite is withdrawn.

5. The declaration under 37 CFR 1.132 filed November 18, 2005 is sufficient to overcome the rejection of claims 1, 13, 14, 15, 16, 19, and 20 under 35 U.S.C. 102(e) as being anticipated by Van Eyk et al. (US 2003/022220 A1), based upon showing that U.S. 2003/0022220 A1 is not an invention "by another".

### **Maintenance of Rejections**

#### ***Claim Rejections - 35 USC § 102***

6. Claims 1, 13, and 14 stand rejected under 35 U.S.C. 102(b) as being anticipated by Mochly-Rosen (U.S. Patent 6,165,977).

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Response to Remarks

Applicant states Mochly-Rosen does not teach a method for identifying an agent or event capable of priming a cell for preconditioning and/or inducing preconditioning based upon any of the claimed preconditioning proteins.

Applicant's arguments filed November 18, 2005 have been fully considered but they are not persuasive. Mochly-Rosen does disclose the use of  $\epsilon$ PKC to screen for compounds effective to induce preconditioning in a cell. Activation of  $\epsilon$ PKC requires  $\text{Ca}^{2+}$  ions, and therefore it is being interpreted to be a  $\text{Ca}^{2+}$  handling protein.

***Claim Rejections - 35 USC § 103***

7. Claims 1, 13, 14, 15, and 20 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Wang, Y. et al. (J. Mol. Cell. Cardiol. 33: 2037-2046 (2001)).

Response to Remarks

Applicant states Wang et al. does not teach or suggest a method for identifying an agent or event capable of priming a cell for preconditioning and/or inducing preconditioning based upon any of the claimed preconditioning proteins.

Applicant's arguments filed November 18, 2005 have been fully considered but they are not persuasive. Wang, Y. et al. does disclose the use of PKC- $\delta$  to screen for compounds effective to induce preconditioning in a cell. Activation of PKC- $\delta$  requires  $\text{Ca}^{2+}$  ions, and therefore it is being interpreted to be a  $\text{Ca}^{2+}$  handling protein.

**New Objections and Rejections**

***Claim Objections***

8. Claim 16 is objected to because of the following informalities:

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9. The abbreviation for the preconditioning protein, IDH in claim 16 should be spelled out. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

10. Claims 1, and 16-18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.
11. In claim 1, it is unclear what is being modulated? Is it the biological activity of the preconditioning protein, or is it the steady state quantity of the protein? What does a  $\text{Ca}^{2+}$  handling protein describe? Would a calcium channel that regulates the flow of calcium ions be a  $\text{Ca}^{2+}$  handling protein, or would a protein that binds  $\text{Ca}^{2+}$  ions, such as PKC be a  $\text{Ca}^{2+}$  handling protein?
12. In claims 16, 17, and 18, what is meant by “level”? Is the level referring to the biological activity or it is referring to the steady state quantity of the protein?

***Claim Rejections - 35 USC § 102***

13. Claims 1, 13, 14, 15, 16, and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by Currie et al. (Brain Research 863: 169-181 (2000)).

Currie et al. disclose an event capable of preconditioning brain tissue. The preconditioning stimulus is produced by occluding the middle cerebral artery by elevation of the middle cerebral artery approximately 0.5 mm from the cortical surface for 10 minutes (see

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Material and Methods, page 170, section 2.2. Ischemic preconditioning stimulation). Currie et al. disclose the induction of chaperone heat shock protein 27 (Hsp27) in the rat cerebral cortex after preconditioning (see page 173, Results section, 3.4. Hsp27 immunoreactivity after PC, and page 175, Figure 4, right panel). Currie et al. state the occlusion of the middle cerebral artery preconditioning method produced a prolonged upregulation of chaperone Hsp27 (see Discussion section, page 174).

14. Claims 1, 13, 14, 15, 16, 19, and 20 are rejected under 35 U.S.C. 102(b) as anticipated by Kobara et al. (J Mol. Cell Cardiol 28: 417-428 (1996)).

Kobara et al. disclose an experimental protocol that compares the effects of ischemic preconditioning on mitochondrial oxidative phosphorylation pathway protein, ATPase (also known as  $F_0F_1$  ATP synthetase) and adenine nucleotide translocase activity. The ischemic preconditioning is achieved by clamping the aortic line for two cycles of a 5-minute period of global ischemia followed by 5-minute period of reperfusion (see page 419, Figure 1, and page 420, Materials and Methods, Measurement of mitochondrial ATPase activity and Measurements of adenine nucleotide translocase sections). Kobara et al. disclose the ATPase activity was consistently higher in the preconditioned group as compared to the control group, either after sustained ischemia, or reperfusion. Kobara et al. state the adenine nucleotide translocase activity was significantly higher in the preconditioned group as compared to the control group after 30 minutes of reperfusion (see page 424, Results, Mitochondrial ATPase and adenine nucleotide translocase activities section, and Figures 7 and 8).

*Conclusion*

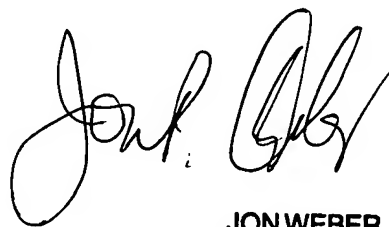
15. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anand U. Desai, Ph.D. whose telephone number is (571) 272-0947. The examiner can normally be reached on Monday - Friday 7:00 a.m. - 3:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber can be reached on (517) 272-0925. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

February 2, 2006



**JON WEBER**  
**SUPERVISORY PATENT EXAMINER**